EXHIBIT D

From: Kargman, Douglas
Sent: 3/6/2006 1:23:38 PM
To: Bruzga, Jill M.
CC: Griesing, Teresa; Raillard, Pierre
Subject: Neurontin Suicide DCA: CONFIDENTIAL

Dear Jill,

I hope you had a nice weekend. Unfortunately, I was sick.

As we discussed at Friday's meeting, I am sending you the Neurontin Suicide DCA (the Lyrica Suicide DCA will be the same). I will ask my colleague Pierre Raillard to forward the Zoloft DCA for comparison.

Best regards,
Douglas

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GABAPENTIN
DATA CAPTURE AID

ABOUT THIS DATA CAPTURE AID – PURPOSE AND RATIONALE

Purpose

The purpose of the Gabapentin Data Capture Aid is to systematically collect and assemble all available information for AEM Report Forms involving adverse events of special interest. A complete list of selected adverse events appears on pages 3-4 of this Data Capture Aid ("**Triggers for Using this Data Capture Aid**").

The Gabapentin Data Capture Aid provides additional lines of inquiry designed to gather supplementary data for certain blocks on the AEM Report Form. The Gabapentin Data Capture Aid is not part of the AEM Report Form and **should not** be used as source documentation.

Implementing this Data Capture Aid will help to ensure an accurate and timely characterization of the reported adverse events including the relative contributions of potential etiological factors to the occurrence of the selected adverse events.

Rationale

Suicidality often occurs in the setting of underlying psychiatric illness, whether diagnosed at the time of the event or afterwards. Furthermore, review of many cases of suicidality reveals existence of medical and/or psychiatric comorbidities as well as concomitant medications. This makes it difficult to determine the causality of the adverse events reported. The following adverse events were selected for intensive surveillance either due to the intrinsic seriousness of the event, the incidence of the event in the clinical development program, or due to possible concerns on the part of Pfizer and/or the regulatory authorities.

For Adverse Experiences Potentially Associated with Suicide/Self-Injury Related Adverse Events:

This Data Capture Aid contains guidelines for collecting specific information to aid in determining the etiology of potentially suicide/self-injury-related adverse events.

Note Compliance should be maintained with all Pfizer SOPs regarding the Adverse Event Monitoring (AEM) System. All instructions for completing an AEM Report Form should also be followed.

WHEN TO USE THE GABAPENTIN DATA CAPTURE AID – TRIGGERS

Triggers For Using This Data Capture Aid

Use the Gabapentin Data Capture Aid when:

1. The suspect drug listed in Drug Data: Block 4-6 is **gabapentin**

AND

2. The patient experienced at least one (or more) of the following selected adverse events:

Triggers For Using This Data Capture Aid

- **Potentially suicide/self-injury related adverse events**
  - **Intentional overdose**
  - **Poisoning deliberate**
  - **Self mutilation**
  - **Depression suicidal**
  - **Completed suicide**
  - **Intentional self-injury**
  - **Self injurious behavior**
  - **Self injurious ideation**
  - **Suicidal ideation**
  - **Suicide attempt**

KEY BLOCKS ON THE AEM REPORT FORM

Key Blocks on the AEM Report Form

The following table lists the blocks on the AEM Report Form where additional data needs to be gathered and a description of the type of data to be gathered:

AEM REPORT FORM BLOCK	TYPE OF DATA TO GATHER
Concomitant Drugs: Block 8	• Use of specific medications (e.g., psychiatric medications)
Narrative: Block 5	• Specific information for potentially suicide/self-injury related adverse events
Patient History: Block 9	• The presence or absence of established risk factors for the adverse event(s)

CONCOMITANT DRUGS: BLOCK 8

Obtain the following additional information and record in **Concomitant Drugs: Block 8**. *Please keep in mind that the examples below in parentheses are not inclusive.*

For **potentially suicide/self-injury related adverse events:**

1. Did the patient take any psychotropic medications within *three months* prior to the onset of the adverse event(s)?

- e.g., thioridazine, mesoridazine, risperidone, olanzapine, quetiapine, clozapine, chlorpromazine, ziprasidone, aripiprazole, pimozide, haloperidol, amitriptyline, imipramine, desipramine, nortriptyline, doxepin, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, etc..,

2. Did the patient take Accutane within three months prior to the onset of the adverse event(s)?

NARRATIVE: BLOCK 5

Obtain the following information and record in **Narrative: Block 5**:

For potentially **suicide/self-injury related adverse events**:

- Obtain information about the event and at the time the event occurred e.g.,
  - inquire about the exact nature of suicidal/self-injurious thoughts, intentions, plans and actions
  - ascertain the gabapentin treatment regimen at the time of the event e.g. amount of medication prescribed, dose at the time of the event, number of days on drug at time of event
  - inquire if the patient was compliant with the dosing regimen of gabapentin, if there had been any change in gabapentin dose and/or treatment regimen (if so, when), prior to, and following the event
  - inquire if treatment with gabapentin was discontinued following event,
  - what other adverse events (in addition to suicide/self-injurious events) were reported
  - if an overdose was involved, inquire whether the overdose was accidental or intentional
  - as a result of the suicide/self-injury related adverse event, did the patient visit the emergency room, require hospitalization,
  - if patient died, elaborate on cause of death and inquire whether an autopsy was performed.
- Ascertain whether the patient had a history of sucide-related events e.g. suicidal thoughts, self-harm, suicidal behaviour, suicide attempts, etc...
- Inquire about the patient's medical and psychiatric diagnosis.
- Inquire about psychiatric comorbidities e.g. bipolar disorder.
- Inquire whether there was a family history of suicide. If so, who.
- Inquire whether there was a family history of psychiatric disorders
- Inquire about concurrent psychosocial stressors.

PATIENT HISTORY: BLOCK 9

Ask the following additional questions and record the information in **Patient History: Block 9**.

1. Does the patient have a prior history of the reported adverse event(s)?

2. Did the patient have any of the following medical conditions or disorders prior to taking gabapentin?

For potentially **suicide/self-injury related adverse events**:

- Personal or family history of suicidal thinking, self-injury or suicide attempts,
- Personal or family history of Major Depressive Disorder, bipolar disorder, alcohol or other substance use (e.g., cocaine, amphetamines, etc.)

Gabapentin Data Capture Aid Summary Sheet

Triggers for Using This Drugs: Block 8
Data Capture Aid

Concomitant

♦ **Potentially Suicide/Self-Injury related**	♦ For potentially **suicide/self-injury related adverse events**
o Intentional overdose o Poisoning deliberate o Self mutilation o Depression suicidal o Completed suicide o Intentional self-injury o Self injurious behavior o Self injurious ideation o Suicidal ideation o Suicide attempt	**1. Did the patient take any psychotropic medications within *three months* prior to the onset of the adverse event(s)?** e.g., thioridazine, mesoridazine, risperidone, olanzapine, quetiapine, clozapine, chlorpromazine, ziprasidone, aripiprazole, pimozide, haloperidol, amitriptyline, imipramine, desipramine, nortriptyline, doxepin, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, etc… **2. Did the patient take Accutane within three months prior to the onset of the adverse event(s)?**

Narrative: Block 5

For potentially **suicide/self-injury related** adverse events

- Obtain information about the event and at the time the event occurred e.g.,
  - inquire about the exact nature of suicidal/self-injurious thoughts, intentions, plans and actions
  - ascertain the gabapentin treatment regimen at the time of the event e.g. amount of medication prescribed, dose at the time of the event, number of days on drug at time of event
  - inquire if the patient was compliant with the dosing regimen of gabapentin, if there had been any change in gabapentin dose and/or treatment regimen (if so, when), prior to, and following the event
  - inquire if treatment with gabapentin was discontinued following event,
  - what other adverse events (in addition to suicide/self-injurious events) were reported
  - if an overdose was involved, inquire whether the overdose was accidental or intentional
  - as a result of the suicide/self-injury related adverse event, did the patient visit the emergency room, require hospitalization,
  - if patient died, elaborate on cause of death and inquire whether an autopsy was performed.
- Ascertain whether the patient had a history of sucide-related events e.g. suicidal thoughts, self-harm, suicidal behaviour, suicide attempts, etc...
- Inquire about the patient's medical and psychiatric diagnosis.
- Inquire about psychiatric comorbidities e.g. bipolar disorder.
- Inquire whether there was a family history of suicide. If so, who.
- Inquire whether there was a family history of psychiatric disorders
- Inquire about concurrent psychosocial stressors.

Patient History: Block 9

Prior history of the reported adverse event(s):

For potentially **suicide/self-injury related adverse events**:

- ♦ Personal or family history of suicidal thinking, self-injury or suicide attempts,
- ♦ Personal or family history of Major Depressive Disorder, bipolar disorder, alcohol or other substance use (e.g., cocaine, amphetamines, etc.)